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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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|-----------------|-------------|----------------------|---------------------|------------------|

09/974,653

10/10/2001

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09/13/2006

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EXAMINER

NGUYEN, VI X

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/974,653

Applicant(s)

BICEK ET AL.

Examiner

Victor X. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17-20,22-27 and 39-55 is/are pending in the application.
- 4a) Of the above claim(s) 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20,22-24 and 39-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. In response to applicant's amendment of 4/17/2006, the examiner has removed all prior 35 USC § 112 rejections.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-20,22-24 and 39-55 are rejected under 35 U.S.C. 102 (b) as being anticipated by Von Oepen et al (U.S. 5,916,264).

Regarding claims 17,40 and 48, Von Oepen et al disclose in fig 1, a stent graft for insertion into target site within a vessel of a patient, including: a main stent (11) has a radially-expandable body, at least one support stent (12) can have an axial length less than the axial length of the body, and a sheath (13) interpose between the body, and the support stent where no portions of the main stent is in contact with the support stent, and the sheath is not bonded to the main stent. Note that the support stent is plastically deformed (in fig. 1 and see col.1, lines 33-36 and lines 51-67) and can generate a force with the main stent to hold the sheath in place

Regarding claims 18-20,41,42 and 50-51, Von Oepen et al disclose the support stent (12) is capable of plastically deformed (see col.1, lines 33-36 and lines 51-67). The sheath (13) can disposes radially outwardly or inwardly of the main stent.

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Regarding claims 22,43-44 and 52-53, Von Oepen et al disclose the support stent (12) has an axial length which is less than the axial length of the body.

Regarding claims 23-24,45-46 and 54-55, Von Oepen et al disclose sheath is selected from the group consisting of a polymeric/a biomaterial sleeve (see col.2, lines 21-24 and lines 30-35). The sheath is also treated with a drug selected from the group consisting of bioactive agents (see col.1, lines 59-61).

Claims 17, 39-40 and 48 are rejected under 35 U.S.C. 102 (b) as being anticipated by Love (U.S.5,865,723).

Regarding claims 17, 39-40 and 48, Love discloses in figures 1-2, a stent graft for insertion into target site within a vessel of a patient, including: a main stent (10) has a radially-expandable body, at least one support stent (14) can have an axial length less than the axial length of the body, and a sheath (12) interpose between the body, and the support stent where no portions of the main stent is in contact with the support stent, and the sheath is not bonded to the main stent. Note that the support stent can be plastically deformed in fig. 1 and can generate a force with the main stent to hold the sheath in place.

### ***Response to Arguments***

3. Applicant's arguments filed 4/17/2006 have been fully considered but they are not persuasive. The applicant argues that Von Oepen reference fails to teach at least one support stent with no portions of the main stent being in contact with at least the support stent. The examiner, respectfully, disagrees. As claim 17 is currently written, it can be interpreted broadly that the Von Oepen reference can provide a sheath 13 along a full length of the device; therefore,

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it will provide no portions of the main stent 11 being in contact with the support stent 12.

Accordingly, the above noted reference is still considered to read on the claimed limitations of the claims noted.

***Conclusion***

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victor X Nguyen  
Examiner  
Art Unit 3734



VN  
8/22/2006



MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER